

## **II. REMARKS**

### **A. Status of the Claims**

Claims 1, 2, and 6-8 were pending in the case at the time of the Action. Claims 3-5 and 9-13 had been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-3, 6-9, and 11-12 have been amended in the Amendment set forth herein. No new claims have been added, and no claims have been canceled.

Exemplary written description support for “curcuminoid” can be found on page 550 of Jang *et al.*, *Planta Med.* 67(6):550-552, 2001 (see C12 in Information Disclosure Statement filed May 5, 2005), which has been specifically incorporated by reference into the patent application (see citation of Jang *et al.* in reference list on page 45, line 3, and statement pertaining to incorporation by reference on page 46, lines 15-20). Jang *et al.* is cited in the specification on page 13, line 27 (ref. 27) and page 15, line 8 (ref. 27). One of ordinary skill in the art, based on the abstract and page 550, paragraphs 1-2, would understand that a “curcuminoid” generally refers to curcumin or an analog or derivative of curcumin. For example, Jang *et al.*, page 550, abstract and second paragraph, sets forth analogs of curcumin, including 1,7-bis(4-hydroxyphenyl)-1,4,6-heptatrien-3-one, procucumenol, and epiprocucumenol.

Further, the term “curcuminoids” is well-known in the art. See, for example, U.S. Patent Application 10/925,814, cited below in the Action, which defines “curcuminoid” as curcumin, demethoxycurcumin, and bisdemethoxycurcumin, or a derivative or analog of these curcuminoid compounds. U.S. Patent App. 10/925,814, para [0031]. See also Mohan *et al.*, *J Biol Chem.* 2000 Apr 7;275(14):10405-12 (C19 in Information Disclosure Statement filed May

5, 2005), U.S. Patent App. Pub. No. 20020058695 (Exhibit 1), published May 16, 2002, and U.S. Patent App. Pub. No. 20020006966 (Exhibit 2), published Jan. 17, 2002.

Thus, there is adequate written description support for “curcuminoid” in the present specification, and this term was well-known in the art at around the time of the priority date of the instant patent application.

Exemplary written description support for “velcade” and “thalidomide” can be found on page 54, lines 6-7.

**B. The Rejections Under 35 U.S.C. §112, Second Paragraph, are Overcome**

Claims 1-2 and 6-8 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants traverse.

According to the Action, it is not clear in claims 1-2 if the methods are *in vivo* or *in vitro* since no subject is recited. Applicant directs the Examiner’s attention to amended claims 1 and 2, which now each recite “*in vivo* or *in vitro*,” thus making it clear that the claims pertain to both *in vivo* and *in vitro* methods.

Written description support for *in vivo* and *in vitro* can be found generally throughout the specification. Exemplary written description support for “*in vivo*” can be found on page 21, lines 10-14 of the specification. Exemplary written description support for “*in vitro*” can be found on page 15, lines 10-12.

According to the Action, claims 1-2 and 6-8 are indefinite because no effective amount is recited. Amended claim 1 in part recites “an amount of a curcuminoid effective to inhibit the proliferation of multiple myeloma cells.” Amended claim 2 in part recites “an amount of a

curcuminoid effective to induce apoptosis in multiple myeloma cells.” Written description support for these amendments can be found generally throughout the specification, such as in originally filed claim 2 and on page 21, lines 10-14.

Amended claim 2 in part recites “contacting said cells with *an effective amount* of curcumin, wherein said curcumin inhibits proliferation of multiple myeloma cells.” Claim 6 has been amended to recite “administering *a therapeutically effective amount* of curcumin to said individual.” (emphasis added). Exemplary written description support for “a therapeutically effective amount” can be found on page 21, lines 10-14 of the specification.

In reviewing a claim for compliance with 35 U.S.C. §112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. §112, second paragraph. See, *e.g.*, *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). In view of the above, Applicant asserts that the claims sufficiently apprise one of ordinary skill in the art of their scope. Therefore, it is respectfully requested that the rejection under 35 U.S.C. §112, second paragraph, should be withdrawn.

### **C. The Rejections Under 35 U.S.C. §102(a) have been Overcome**

Claims 1-2 have been rejected under 35 U.S.C. §102(a) as being anticipated by CAPLUS DN 139:30341 (*Blood* 101:1053-1062, 2003; Bharti *et al.*, hereinafter “Bharti”). Bharti is said to disclose that curcumin suppresses the proliferation of and induces apoptosis in multiple myeloma cells. Applicant traverses.

It is respectfully submitted that Bharti is not prior art. Applicant has herein attached a declaration of the inventor (Exhibit 3) demonstrating that Bharti is a publication of the inventor describing his own invention. This declaration is set forth in accordance with *In re Katz*, which establishes the ability to remove an inventor's own art as prior art where the non-inventor co-author of cited art is acting under inventor's direction and control. *In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (CCPA 1982).

The declaration of the inventor submitted herein sets forth the role that each of the non-inventor authors played with respect to the subject matter of Bharti, indicating that "[e]ach of these individuals operated under my direction with respect to the studies that the individual carried out, and did not contribute conceptually to the subject matter of the invention." Declaration, paragraph 5. As such, Bharti is not available as prior art.

Therefore, in view of the above, Applicant respectfully requests that the rejection of claims 1 and 2 under 35 U.S.C. §102(a) as being anticipated by Bharti should be withdrawn.

#### **D. The Rejections Under 35 U.S.C. §103(a) have been Overcome**

Claims 6-8 have been rejected under 35 U.S.C. §103(a) as being anticipated by CAPLUS DN 139:30341 (*Blood* 101:1053-1062, 2003; Bharti *et al.*, hereinafter "Bharti"). Bharti is said to disclose that curcumin suppresses the proliferation of and induces apoptosis in myeloma cells, and that it would be obvious to one of ordinary skill in the art that a compound that suppresses proliferation of and induces apoptosis in multiple myeloma cells would be useful to treat multiple myeloma in an individual. Applicant traverses.

As set forth above, Bharti is not prior art. Applicant has attached a declaration of the inventor (Exhibit 3) demonstrating that Bharti is a publication of the inventor describing his own

invention. This declaration is set forth in accordance with *In re Katz*. *In re Katz*, 687 F.2d 450, 215 U.S.P.Q. 14 (CCPA 1982).

Therefore, in view of the above, Applicant respectfully requests that the rejection of claims 1 and 2 under 35 U.S.C. §102(a) as being anticipated by Bharti should be withdrawn.

**E. The Rejections Under the Judicially Created Doctrine of Obviousness-Type Double Patenting have been Overcome**

Claims 1-2 and 6-8 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 10-17, and 22-23 of copending Application No. 10/925,814. Applicant traverses.

Applicants understand that this rejection is merely *provisional* since the grounds for the rejections are two patent applications, not issued patents. *Manual of Patent Examining Procedure (MPEP)* § 804 (I)(B). According to the *MPEP* § 804 (I)(B), a provisional rejection must be withdrawn if the claims are otherwise allowable. The primary purpose of the provisional double-patenting rejection is for its notice function for the Applicant, so they Applicants can plan and proceed accordingly. Nevertheless, Applicants will remove this issue by filing a terminal disclaimer. Therefore, this provisional rejection should be withdrawn.

**F. Conclusion**

In light of the foregoing, Applicants assert that all claims are in condition for allowance, and an early indication to that effect is earnestly solicited.

### **III. REQUEST FOR EXTENSION OF TIME**

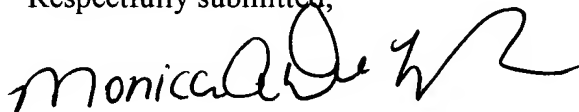
Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions for an extension of time of one months to and including December 8, 2005.

Pursuant to 37 C.F.R. § 1.17, a check in the appropriate amount for a process fee for a one-month extension of time is enclosed.

If the check is inadvertently omitted, or should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, or should an overpayment be included herein, the Commissioner is authorized to deduct or credit said fees from or to Fulbright & Jaworski Deposit Account No. 50-1212/CLFR:234US.

Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-5639.

Respectfully submitted,



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